

510(k) SUMMARY

SEP - 4 2009

Manufacturer: Atlas Spine, Inc.
Address: 1555 Jupiter Park Drive, Suite # 4
Jupiter, FL 33458
Telephone: 561-741-1108
Fax: 561-741-1870

Official Correspondent: Jeannette G. Dailey
Title: Vice President Regulatory Affairs &
Quality Assurance
Telephone: 561-354-4319

Device Classification: Intervertebral body fusion device
Class II per 21 CFR §888.3080
Product Code: MAX

Spinal intervertebral body fixation orthosis
Class II per 21 CFR §888.3060
Product Code: MQP

Trade/Proprietary Name: Atlas Spine Spacer

Common Names: Intervertebral Body Fusion Device [IBFD]
Vertebral Body Replacement [VBR]

Predicate Devices: Atlas Spine Vertebral Body Replacement
Atlas Spine, Inc.
K063205

SeaSpine Spacer System
SeaSpine, Inc.
K082310

Intended Use:

Intervertebral Body Fusion Device: The Atlas Spine Spacer is indicated for intervertebral body fusion procedures in skeletally mature patients with degenerative disc disease (DDD) at one or two contiguous levels from L2-S1. DDD is defined as discogenic back pain with degeneration of the disc confirmed by patient history and radiographic studies. These DDD patients may also have up to Grade I spondylolisthesis or retrolisthesis at the involved levels(s). This device is to be used with autogenous bone graft. The Atlas

Atlas Spine, Inc.

510(k) Premarket Notification: Atlas Spine Spacer

Spine Spacer is to be used with supplemental fixation. Patients should have at least six (6) months of non-operative treatment prior to treatment with an intervertebral cage.

Vertebral Body Replacement: When used as a vertebral body replacement, the Atlas Spine Spacer is intended for use in the thoracolumbar spine (T1-L5) for partial or complete replacement (i.e., vertebrectomy) of a diseased vertebral body resected or excised for the treatment of tumors in order to achieve anterior decompression of the spinal cord and neural tissues, and to restore the height of a collapsed vertebral body. The Atlas Spine Spacer is also indicated for treating fractures of the thoracic and lumbar spine.

The Atlas Spine Spacer is designed to restore the biomechanical integrity of the anterior, middle and posterior spinal column, even in the absence of fusion for a prolonged period of time. The interior of the Atlas Spine Spacer can be packed with autograft and/or allograft. The device must be used with supplemental internal fixation systems cleared for the conditions listed above (i.e., tumor or trauma of T1-L5).

Device Description:

The Atlas Spine Spacer is a rectangular, radiolucent device provided in various sizes. The device design includes six radiopaque markers that allow postoperative radiographic confirmation of the device position and orientation.

Equivalence to Marketed Product

The Atlas Spine Spacer was shown to be substantially equivalent to previously cleared devices and has the same indications for use, design, function and material.

Performance Data

Pre-clinical data per ASTM F2077 have been submitted to characterize the Atlas Spine Spacer.



DEPARTMENT OF HEALTH & HUMAN SERVICES

SEP - 4 2009

Food and Drug Administration
10903 New Hampshire Avenue
Document Mail Center - WO66-G609
Silver Spring, MD 20993-0002

Atlas Spine, Inc.
% Ms. Jeannette Daily
Vice President of Regulatory Affairs and Quality Assurance
1555 Jupiter Park Drive, Suite 4
Jupiter, Florida 33458

Re: K091406
Trade/Device Name: Atlas Spine Spacer
Regulation Number: 21CFR 888.3060
Regulation Name: Spinal intervertebral body fixation orthosis
Regulatory Class: II
Product Code: MQP, MAX
Dated: August 28, 2009
Received: September 1, 2009

Dear Ms. Daily:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

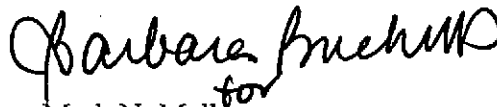
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to <http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm> for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to <http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address <http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,

A handwritten signature in black ink that reads "Barbara Melkerson" with a small "for" written below the name.

Mark N. Melkerson
Director
Division of Surgical, Orthopedic,
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): _____

Device Name: Atlas Spine Spacer

Indications for Use:

Intervertebral Body Fusion Device: The Atlas Spine Spacer is indicated for intervertebral body fusion procedures in skeletally mature patients with degenerative disc disease (DDD) at one or two contiguous levels from L2-S1. DDD is defined as discogenic back pain with degeneration of the disc confirmed by patient history and radiographic studies. These DDD patients may also have up to Grade 1 spondylolisthesis or retrolisthesis at the involved levels(s). This device is to be used with autogenous bone graft. The Atlas Spine Spacer is to be used with supplemental fixation. Patients should have at least six (6) months of non-operative treatment prior to treatment with an intervertebral cage.

Vertebral Body Replacement: When used as a vertebral body replacement, the Atlas Spine Spacer is intended for use in the thoracolumbar spine (T1-L5) for partial or complete replacement (i.e., vertebrectomy) of a diseased vertebral body resected or excised for the treatment of tumors in order to achieve anterior decompression of the spinal cord and neural tissues, and to restore the height of a collapsed vertebral body. The Atlas Spine Spacer is also indicated for treating fractures of the thoracic and lumbar spine.

The Atlas Spine Spacer is designed to restore the biomechanical integrity of the anterior, middle and posterior spinal column, even in the absence of fusion for a prolonged period of time. The interior of the Atlas Spine Spacer can be packed with autograft and/or allograft. The device must be used with supplemental internal fixation systems cleared for the conditions listed above (i.e., tumor or trauma of T1-L5).

Prescription Use X
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use _____
(21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE
OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Kareem S. Buremy for MXM
(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K091404